Barr Laboratories, Inc.

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Citizen Petition

September 4, 2002

Dockets Management Branch
Food and Drug Administration (HFA-305)
5630 Fishers Lane Room 1061
Rockville, Maryland 20852

On behalf of the petitioner, Barr Laboratories, the undersigned submits this petition in quadruplicate pursuant to 21 CFR 10.30 and in accordance with the regulation at 21 CFR 314.161, requesting that the Commissioner of the Food and Drug Administration provide a determination whether a listed drug has been discontinued for reasons of safety or effectiveness.

A. Action Requested

The petitioner request that the Commissioner of the Food and Drug Administration determine whether Niaspan® (Niacin Extended Release Tablets, 500 mg), NDA 020381 sponsored by KOS Pharmaceuticals, Inc., have been voluntarily discontinued from marketing or withheld from sale for reasons of safety or effectiveness.

B. Statement of Grounds

The publication, ***Approved Drug Products with Therapeutic Equivalence Evaluations*** (the List, or Orange Book), identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act). The main criterion for the inclusion of any product is that the product is subject of an application with an effective approval that has not been withdrawn for safety or efficacy reasons. The List also identifies approved products that have never been marketed, have been discontinued from marketing, or have had their approvals withdrawn for other than safety or efficacy reasons subsequent to being discontinued from marketing.

Niaspan® (Niacin Extended Release Tablets, 500 mg), NDA 020381 sponsored by KOS Pharmaceuticals, was approved by FDA on July 28, 1997. However, it is now listed in the discontinued section of the Orange Book. Therefore, because the NDA holder has discontinued marketing of this drug product, Barr Laboratories requests that the FDA determine whether KOS Pharmaceuticals, Inc. decision to discontinue marketing Niaspan® (Niacin Extended Release Tablets, 500 mg) was for reasons of safety or effectiveness.

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C. Environmental Impact

A claim for categorical exclusion of the requirement for submission of an environmental assessment is made pursuant to 21 CFR 25.31.

D. Economic Impact

Pursuant to 21 CFR 10.30(b), economic impact information is to be submitted only when requested by the Commissioner. This information will be provided if so requested.

E. Certification

The undersigned certifies that to the best of its knowledge and belief, the petition includes all information and views on which the petitioner relies, and that it includes representative data and information known to the petitioner that are unfavorable to the petition.

Sincerely,

Nicholas Tantillo
Senior Director, Regulatory Affairs

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BARR LABS
300 CORPORATE DRIVE
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BLAUVELT, NY 10913

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